



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with the Q-Submission Program for medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0530 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission Program for Medical Devices." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Q-Submissions Program for Medical Devices

OMB Control Number 0910-0756--Revision

The guidance entitled “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” (<https://www.fda.gov/media/114034/download>) provides an overview of the mechanisms available to submitters through which they can request feedback from, or a meeting with, FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides

recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submission types and other uses of the Q-Submission Program.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,700 submissions is based on recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is needed to prepare a Q-Submission.

Early Payor Feedback Program

Prior to submitting a Pre-Submission, medical device sponsors may request that one or more payor organizations join a Pre-Submission meeting. Payors include public payors such as Centers for Medicare & Medicaid Services, private health plans, health technology assessment groups, and others who provide input into coverage, procurement, and reimbursement decisions. To facilitate such opportunities to obtain payor input, FDA provides information about our Early Payor Feedback Program (EPFP) and a list of current payor participants on our website (<https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force#2>). For payors to decide which devices to provide feedback on, we have developed a voluntary form for manufacturers to provide basic information regarding their device. This form is shared with the payors from whom the manufacturer is requesting feedback. We expect preparation and submission of the form to take no more than 2 hours.

eSTAR for Q-Submissions

Under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52), and consistent with the Medical Device User Fee Amendments 2017 (MDUFA IV) Commitment Letter and the FDA guidance document entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" (<https://www.fda.gov/media/131064/download>),

FDA has developed an “electronic Submission Template and Resource” (eSTAR) for Q-submissions to facilitate the preparation of submissions in electronic format (<https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program>). The use of eSTAR for Q-Submissions is currently voluntary. We assume approximately 40 percent of Q-Submissions will use eSTAR and that preparation using eSTAR will take approximately half the time of preparing a submission without using eSTAR.

We estimate a setup burden of 5 minutes for new eSTAR users. Respondents will only need to set up eSTAR the first time they use it. We note that because some respondents may have already undergone eSTAR set up for other types of submission, e.g., premarket notification, fewer respondents may need to undergo eSTAR setup than estimated.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”					
Q-Submissions:					
CDRH	2,160	1	2,160	137	295,920
CBER	60	1	60	137	8,220
Q-Submissions using eSTAR (21 CFR part 814, subparts A through E; section 745A(b) of the FD&C Act):					
CDRH	1,440	1	1,440	69	99,360
CBER	40	1	40	69	2,760
eSTAR setup	1,480	1	1,480	0.08 (5 minutes)	118
Manufacturer request to participate in EPFP	30	1	30	2	60
Total					406,438

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Including the EPFP form represents a revision to this information collection request. Our estimated burden for the information collection reflects the availability of eSTAR to assist electronic preparation of Q-submissions and addition of the EPFP form, resulting in an overall decrease of 85,803 hours.

Dated: August 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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